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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,938	10/31/2001	Salvatore Albani	UCSD1360-1	8878
7590 12/15/2003			EXAMINER	
LISA A. HAILE PH.D. GRAY CARY WARE & FREIDENRICH LLP 4365 EXECTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 12/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/001,938	ALBANI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	G. R. Ewoldt, Ph.D.	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

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|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-14, 13-18, 25-27 and 31-56, drawn to method of modulating the immune response comprising augmenting or inducing an inflammatory response in a patient, said method comprising administering a dnaJ HSP peptide, classified in Class 424, subclass 278.1.

II. Claims 1-12, 15, 19-24, and 28-56, drawn to method of modulating the immune response comprising tolerizing or inhibiting an inflammatory response in a patient, said method comprising administering a dnaJ HSP peptide, classified in Class 424, subclass 278.1.

III. Claims 57-66, drawn to a peptide or a combination of peptides, classified in Class 424, subclass 278.1 and Class 530, subclasses 326 and 327.

IV. Claims 67-73, drawn to a nucleic acid, or a combination of nucleic acids, a vector, and a host cell, classified in Class 435, subclasses 69.1, 252.3, 320.1.

2. Inventions I and II are different methods. Note that methods of inducing an inflammatory response and methods of inhibiting an inflammatory response would be mutually exclusive. Therefore they are patentably distinct.

3. Invention III and IV are different products. They are distinct because their structures and/or modes of action are different. Therefore, the Invention are patentably distinct.

4. The nucleic acid of Invention IV is related to the peptide of Invention III by virtue of encoding same. However, nucleic acids and polypeptides are physically and functionally distinct chemical entities. Therefore, the Inventions are patentably distinct.

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5. Inventions III and I-II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in materially different processes, such as to produce antibodies in *in vitro* assays.

6. This application contains inventions drawn to patentably distinct species. Regardless of Group chosen, Applicant is further required under 35 U.S.C. § 121 to elect:

A) a **specific** peptide or polynucleotide encoding a specific peptide, or a combination of peptides or a combination of polynucleotides encoding specific peptides, such as those listed in Claims 4, 10, or 12,

B) should Applicant elect either Group I or II Applicant is further required to elect a specific pathological (disease) state, such as one of those listed in Claims 33 or 35.

C) and list all Claims readable thereon including those subsequently added. Currently Claims 1-33 and 35-73 are generic.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different peptides comprise discrete sequences that would likely bind different immune-mediating receptors. The different diseases comprise different pathologies etiologies and expected outcomes. Therefore, the species are independent and patentable over one another.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful,


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the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

**Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
12/10/03  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**